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| 10/578,719 | 05/09/2006 | Cheong-Ho Chang | P6106/Namy | 3405 |

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| EXAMINER | |
|---|---|
| YEAGER, RAYMOND P | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/578,719 | CHANG ET AL. | |
| | Examiner | Art Unit | |
| | Raymond P. Yeager | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03/26/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1 to 12 are pending.

### *Election/Restriction*

Applicant's election of group I, claims 1 to 6 in the reply filed on 02/02/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7 to 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/26/2010.

Applicant's election without traverse collagen as the elected species in the reply filed on 03/26/2010 is acknowledged.

### *Claim Rejections – 35 USC § 112 Second Paragraph*

The following is a quotation of the second paragraph of 35 USC 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites "*one antibiotic, such as*" or "*one antifungal agent, such as*" wherein it is unclear if the "*such as*" clause is provided as guidance for structural limitations, functional limitations, or other limitations imparted for each group. Regarding claim 5, the phrase "*such as*" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). As such the metes and bounds of this claim are unclear, rendering the claim indefinite.

***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 USC 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,413,511 (Publication date: 07/02/2002), hereafter referred to as the Glorioso patent.

Applicant claims a composition comprising chondrocytes (more than 106 cells/mL), thrombin, and fibrinogen

The Glorioso patent teaches a composition comprising chondrocytes, collagen, fibrinogen, and thrombin wherein the composition provides for autologous transplantation to the cartilage in the joint (abstract, column 13, lines 1-25; column 19, lines 25-38; and claims 1 and 14 to 16). The composition comprises $10^6$ to $10^7$ cells/mL wherein the cells are harvested with an enzyme and then incubated in cell media (columns 32-34, example V and columns 45-46, example XVI). The reference anticipates the claim subject matter.

- Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,904,259 (Publication date: 02/27/1990), hereafter referred to as the Itay patent.

Applicant claims a composition comprising chondrocytes (more than 106 cells/mL), thrombin, and fibrinogen (20 to 200 mg/mL).

The Itay patent teaches a composition to repair the defects in cartilage wherein the composition comprises $8x10^7$ to $1.6x10^8$ cells/mL, 100 to 150 mg/mL of fibrinogen, and thrombin, wherein the chondrocytes may be autologous, are harvested with an enzyme, and incubated in cell media (column 2, line 35 to column 3, line 7 and column 5, paragraph 2). The Itay reference also teaches the composition comprises 2,000KIU/mL of aprotonin which is a anticipates the genus of the species components

in instant claim 6 ("*at least one component selected from: 0.01 mg/mL to 20 mg/mL of collagen, 0.1 mg/mL to 20 mg/mL of hyaluronic acid and 0.1 mg/mL to 20 mg/mL of glycosaminoglycan (GAG), or 1 to 3000 KIU/mL of aprotinin*"). The reference anticipates the claim subject matter.

- Claims 1 to 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/03160 (Publication date: 02/08/1996), hereafter referred to as the Vacanti publication.

Applicant claims a composition comprising chondrocytes (more than 106 cells/mL), thrombin, and fibrinogen (20 to 200 mg/mL).

The Vacanti publication teaches a suspension comprising chondrocytes ($12.5x10^6$ cells/mL), fibrinogen (39.8 to 58.9 mg/mL), and thrombin (pages 12-16, examples 1-2; and claims 15-17). The chondrocytes are harvested with an enzyme from cartilage and incubated in cell media (page 8). The reference anticipates the claim subject matter.

- Claim 1 to 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Passaretti et al, 2001 (*Tissue Engineering*, vol. 7(6):805-815; as provided in the 02/02/2010 restriction).

Applicant claims a composition comprising chondrocytes (more than 106 cells/mL), thrombin (0.01 to 50 IU/mL), and fibrinogen (20 to 200 mg/mL).

Passaretti et al, 2001 teaches a tissue-engineered cartilage composition comprising isolated autologous chondrocytes ($40x10^6$ cells/mL), fibrinogen (80 to 160 mg/mL), and thrombin (50 units/mL i.e. 50 IU/mL) (abstract; and page 807, paragraphs 3 and 4). The chondrocytes are harvested from cartilage using an enzyme and the cells are incubated in cell media (pages 806-807, chondrocyte isolation section). The reference anticipates the claim subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 USC 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- Claims 1 to 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passaretti et al, 2001 (*Tissue Engineering*, vol. 7(6):805-815; as provided in the 02/02/2010 restriction), as in claims 1 to 4 above, and further in view of US Patent 5,972,385 (Publication date: 10/26/1999), hereafter referred to as the Liu patent.

Applicant claims a composition comprising chondrocytes (106 cells/mL), thrombin (0.01 to 50 IU/mL), and fibrinogen (20 to 200 mg/mL). The composition further comprises an antibiotic or antifungal agent and collagen (0.01 to 20 mg/mL).

As discussed *supra*, Passaretti et al, 2001 teaches a tissue-engineered cartilage composition comprising isolated autologous chondrocytes ($40x10^6$ cells/mL), fibrinogen (80 to 160 mg/mL), and thrombin (50 units/mL i.e. 50 IU/mL) wherein the chondrocytes are harvested from cartilage using an enzyme and the cells are incubated in cell media (limitations in instant claims 1 to 4).

Passaretti et al, 2001 does not expressly teach the presence of collagen. This deficiency in Passaretti et al, 2001 is cured by the teachings of the Liu patent. The Liu patent teaches patent teaches a matrix or the support of cartilage repair in the form of a fibrin-collagen tissue equivalent which comprises 20 mg/mL collagen, 20 mg/mL fibrinogen, and 2 U/mL of thrombin (columns 14-15, examples 7 and 8). This collagen-fibrinogen-thrombin matrix is a competent support matrix for chondrocytes which are isolated from cartilage (column 5, lines 42-67). Further, it would be obvious to one of ordinary skill in the art to include anti-infectives in the therapeutic composition (limitations in instant claim 5) (see MPEP 2144.03).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a cartilage therapeutic composition comprising enzyme-treated, isolated, and cultured autologous chondrocytes, fibrinogen, and

thrombin as taught by Passaretti et al, 2001 and provide collagen within the fibrinogen-thrombin support matrix as taught by the Liu patent. One of ordinary skill in the art would have been motivated to do this because Passaretti et al, 2001 teaches a tissue-engineered cartilage comprising a matrix with chondrocytes are appropriate for the clinical application of cell-based therapy (page 814, paragraph 2), the Liu patent teaches collagen-fibrinogen-thrombin matrices are appropriate matrices for carrying chondrocytes for cartilage repair column 5, lines 54-67; and column 8, lines 32-41). In light of the forgoing discussion, it would be obvious to one of ordinary skill in the art that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

- Claims 1 to 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passaretti et al, 2001 (*Tissue Engineering*, vol. 7(6):805-815; as provided in the 02/02/2010 restriction), US Patent 5,972,385 (Publication date: 10/26/1999), hereafter referred to as the Liu patent, and US patent application publication 2002/0025921 (Publication date: 02/28/2002), hereafter referred to as the Petito publication.

Applicant claims a composition comprising chondrocytes (106 cells/mL), thrombin (0.01 to 50 IU/mL), and fibrinogen (20 to 200 mg/mL). The composition further comprises an antibiotic or antifungal agent and collagen (0.01 to 20 mg/mL).

As discussed *supra*, the combination of Passaretti et al, 2001 and the Liu patent teaches a tissue-engineered cartilage composition comprising isolated autologous chondrocytes ($4x10^7$ cells/mL), collagen (20 mg/mL), fibrinogen (20 mg/mL), and thrombin (2 IU/mL) wherein the chondrocytes are harvested from cartilage using an enzyme and the cells are incubated in cell media.

The combination of Passaretti et al, 2001 and the Liu patent does not expressly teach the presence an antibiotic or antifungal agent but this deficiency is cured by the

teachings of the Petito publication. The Petito publication teaches a collagen composition for cartilage repair (abstract; and paragraph 77-78). The Pettito publication also teaches the incorporation of antibiotics such as streptomycin in the composition (paragraphs 94-95, 102-103).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a cartilage therapeutic composition comprising enzyme-treated, isolated, and cultured autologous chondrocytes, collagen, fibrinogen, and thrombin as taught by the combination of Passaretti et al, 2001 and the Liu patent. One of ordinary skill in the art would have been motivated to do this because Passaretti et al, 2001 teaches a tissue-engineered cartilage comprising a matrix with chondrocytes are appropriate for the clinical application of cell-based therapy (page 814, paragraph 2), the Liu patent teaches collagen-fibrinogen-thrombin matrices are appropriate matrices for carrying chondrocytes for cartilage repair column 5, lines 54-67; and column 8, lines 32-41), and the Petito publication teaches a cartilage repair composition comprising collagen and an antibiotics enhance the bacteriostatic quality of the composition and promote the healing of cartilage (abstract; and paragraphs 2, 77, and 102-103). In light of the forgoing discussion, it would be obvious to one of ordinary skill in the art that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Conclusion***

No claims are allowed; all claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond P. Yeager whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Thurs 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

/Leon B Lankford/
Primary Examiner, Art Unit 1651